IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

ROCHE PALO ALTO LLC ET AL,

Plaintiff,

v.

APOTEX, INC. ET AL,

Defendant.
_____/

No. C05-02116 MJJ

ORDER GRANTING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

INTRODUCTION

Before the Court is Plaintiffs Roche Palo Alto LLC and Allergan, LLC's Motion For Summary Judgment. (Docket No. 52.)

For the following reasons, the Court **GRANTS** the Motion, as described in more detail below.

FACTUAL BACKGROUND

This case involves the same parties, and the same patent, as a previous matter litigated to judgment before this Court: *Syntex v. Apotex*, Case No. 3:01-cv-02214 MJJ ("*Syntex*"). As with *Syntex*, this case is about Defendants' proposal, in an Abbreviated New Drug Application ("ANDA") filed with the FDA, to make and sell a ketorolac tromethamine ("KT") ophthalmic solution, and whether that solution would infringe U.S. Patent No. 5,110,493 ("the '493 Patent") under 35 U.S.C. § 271(e)(2).

A. The Prior *Syntex* Litigation.

In the earlier *Syntex* litigation, Plaintiffs filed a complaint alleging that Defendants' ANDA 76-109 formulation infringed the '493 Patent. The drug for which Defendants sought approval pursuant to ANDA 76-109 was a 0.5% KT ophthalmic solution that was a generic copy of a 0.5% KT ophthalmic solution marketed by Plaintiffs known as ACULAR®. In *Syntex*, Defendants disputed whether their ANDA 76-109 formulation infringed the '493 Patent, and also argued (in the form of both affirmative defenses and counterclaims) that the '493 Patent was invalid and unenforceable. Specifically, with respect to invalidity, Defendants contended that the '493 patent was invalid on the grounds that it lacked utility, lacked enablement, failed to disclose the best mode, was indefinite, and was obvious. With respect to unenforceability, Defendants contended that Plaintiffs had committed inequitable conduct in prosecuting the '493 Patent.

After issuing a claim construction order, this Court granted summary judgment of infringement in favor of Plaintiffs in *Syntex*. The Court then conducted a bench trial on the issues of invalidity and unenforceability of the '493 Patent, and issued Findings of Fact and Conclusions of Law that determined that the '493 Patent was valid and enforceable.

On an appeal brought by Defendants, the Federal Circuit affirmed this Court's claim construction and determination that there was no inequitable conduct, but remanded the case to this Court for further consideration of obviousness. *See Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371 (Fed. Cir. 2005). After further briefing and hearing on remand, this Court issued further Findings of Fact and Conclusions of Law in which it found, for a second time, that the '493 patent was not invalid based on obviousness. On a second appeal by Defendants, the Federal Circuit subsequently affirmed, in an April 9, 2007 order, this Court's determination that the '493 Patent is not invalid and is non-obvious.

On April 30, 2007, the Supreme Court issued its decision in *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007) addressing the standards by which obviousness should be adjudicated. On May 3, 2007, contending that the *KSR* decision constituted a change in the law of obviousness, Defendants filed a motion with the Federal Circuit requesting that the Federal Circuit recall and stay its mandate in Syntex and accept a petition for rehearing by panel or *en banc*. The

Federal Circuit summarily denied Defendants' motion on June 5, 2007. On July 9, 2007, Defendants filed a petition for a writ of certiorari with the United States Supreme Court, seeking to have the Federal Circuit's April 9, 2007 decision summarily vacated and remanded. That petition is still pending.

B. The Current Litigation.

In 2005, Defendants submitted a second ANDA (ANDA 77-308) to the FDA, seeking approval for an 0.4% KT ophthalmic solution which would be a generic copy of a 0.4% KT ophthalmic solution marketed by Plaintiffs known as ACULAR LS®. Plaintiffs filed the complaint in this action against Defendants in May 2005, alleging that the ANDA 77-308 formulation infringes the '493 Patent. In their amended answer, Defendants contend that the ANDA 77-308 formulation does not infringe. They also again argue (in the form of both affirmative defenses and counterclaims) that the '493 Patent is invalid and unenforceable. With respect to invalidity, Defendants this time contend that the '493 patent is invalid on the grounds that it lacks utility, lacks enablement, fails to disclose the best mode, is indefinite, is obvious, and constitutes obviousness-type double patenting. With respect to unenforceability, Defendants again contend that Plaintiffs committed inequitable conduct in prosecuting the '493 Patent.

LEGAL STANDARD

Rule 56(c) of the Federal Rules of Civil Procedure authorizes summary judgment if there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). The moving party bears the initial burden of demonstrating the basis for the motion and identifying the portions of the pleadings, depositions, answers to interrogatories, affidavits, and admissions on file that establish the absence of a triable issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). If the moving party meets this initial burden, the burden then shifts to the non-moving party to present specific facts showing that there is a genuine issue for trial. Fed. R. Civ. P. 56(e); *Celotex*, 477 U.S. at 324; *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986). The non-movant's bare assertions, standing alone, are insufficient to create a material issue of fact and defeat a motion for summary judgment. *Anderson*, 477 U.S. at 247-48. An issue of fact is material if, under the

substantive law of the case, resolution of the factual dispute might affect the case's outcome. *Id.* at 248. Factual disputes are genuine if they "properly can be resolved in favor of either party." *Id.* at 250. Thus, a genuine issue for trial exists if the non-movant presents evidence from which a reasonable jury, viewing the evidence in the light most favorable to that party, could resolve the material issue in its favor. *Id.* However, "[i]f the [non-movant's] evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Id.* at 249-50 (internal citations omitted).

ANALYSIS

A. Plaintiffs Are Entitled To Summary Judgment Of Infringement.

Submission of an ANDA is an act of patent infringement if the ANDA seeks approval for a drug that is claimed in a patent or the use of which is claimed in a patent. 28 U.S.C. § 271(e). Determination of patent infringement is a two-step analysis. The first step is to construe, or interpret, a claim of the patent. *See Gart v. Logitech, Inc.*, 254 F.3d 1334, 1339 (Fed. Cir. 2001). The second step is to determine whether every limitation of the properly construed claim is found in the accused device, either literally or under the doctrine of equivalents. *See id.*

1. Defendants Do Not Dispute That Each Limitation Of Claims 1-5, 15 & 16 Literally Reads On The ANDA 77-308 Formulation.

Plaintiffs contend that Defendants have admitted, in responses to requests for admission, that all of the claim limitations contained in claims 1-5, 15 and 16 of the 493 Patent literally read on the ANDA 77-308 formulation. The Court agrees.

Determination of which terms in the '493 Patent claims constitute claim limitations, and construction of those terms deemed limitations, was previously addressed by this Court in *Syntex*. At that time, this Court determined that the Court determined that "stabilizing" and "antimicrobially effective" are not claim limitations, and arrived at constructions of the other limitations. Defendants do not challenge the correctness of this Court's prior claim construction rulings here, and in any event, issue preclusion would prevent Defendants from relitigating these claim construction issues. *See Del Mar Avionics, Inc. v. Guinton Instrument Co.*, 836 F.2d 1320, 1323 (Fed. Cir. 1987). The Court's claim constructions from *Syntex* are binding on Defendants.

Defendants also do not dispute that their responses to Plaintiffs' requests for admission admit that each of the limitations of claims 1-5 & 15-16 of the '493 Patent is literally met by the ANDA 77-308 formulation. (*See* Shafroth Decl., Exh. 4, Admitted Request For Admission Nos. 1-5, 7, 12 (for claims 1-4); *id.*, Admitted Request For Admission Nos. 1-5, 7, 12-14, 16-17, 19-20 (for claim 5); *id.*, Admitted Request For Admission Nos. 2-5, 7, 22 (for claims 15-16).) The Court therefore finds that it is undisputed that each of the limitations of claims 1-5 & 15-16 of the '493 Patent is literally met by the ANDA 77-308 formulation.

2. Because Defendants' Reverse Doctrine of Equivalents Argument Lacks Any Support In The Claims, Specification, Prosecution History or Prior Art, It Fails As A Matter Of Law.

Defendants contend that summary judgment of infringement is nonetheless inappropriate because they have raised a triable issue of fact as to whether the reverse doctrine of equivalents defense precludes a finding of infringement. The Court finds, however, that Defendants' reverse doctrine of equivalents argument lacks any support in the '493 Patent's claims, specification, prosecution history, or prior art, and therefore fails as a matter of law.

Under the reverse doctrine of equivalents, "where a device is so far changed in principle from a patented article that it performs the same or a similar function in a substantially different way, but nevertheless falls within the literal words of the claim, the doctrine of equivalents may be used to restrict the claim and defeat the patentee's action for infringement." *Graver Tank & Mfg. Co. v. Linde Air Prod. Co.*, 339 U.S. 605, 608-09 (1950) (citations omitted). Once a patentee shows claims literally read on accused product, the burden of showing nonequivalence under this doctrine shifts to the accused infringer. *See Del Mar Avionics*, 836 F.2d at 1325 (Fed. Cir. 1987) (finding accused infringer had not "carried the burden of its argument" when invoking the reverse doctrine of equivalents); *Tate Access Floors, Inc. v. Interface Architectural Resources, Inc.*, 279 F.3d 1357, 1368 (Fed. Cir. 2002) (referring to reverse doctrine of equivalents as a "defense to literal

infringement").[1]

The reverse doctrine of equivalents is an equitable doctrine that was judicially created to prevent unwarranted extension of the claims of a patent beyond a fair scope of the patentee's invention. *See Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.3d 1565, 1581 (Fed. Cir. 1991). The equitable scope, or "principle", of the invention must in the first instance be determined from evidence in the public record. *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1581 (Fed. Cir. 1991) ("Application of the [reverse doctrine of equivalents] requires that facts specific to the accused device be determined and weighed against the equitable scope of the claims, ***which in turn is determined in light of the specification, the prosecution history, and the prior art***.") (emphasis added). To prevail on their reverse doctrine of equivalents defense, Defendants must as a threshold matter establish a "principle" of the patented invention by reference to the claim language, specification, prosecution history, and/or prior art that this Court can then compare to the principle of the accused product. *See Ciena Corp. v. Corvis Corp.*, 334 F.Supp.2d 598, 604-05 (D. Del. 2004); *U.S. Steel Corp. v. Phillips Petroleum Co.*, 865 F.3d 1247, 1253 n.9 (Fed. Cir. 1989).

Here, Defendants contend that the "principle" of the '493 invention is the use of Octoxynol 40 to provide "robust" stability to the '493 formulations by forming micelles to prevent interaction between ketorolac tromethamine ("KT") and benzalkonium chloride ("BAC"). Defendants contend that their ANDA 77-308 formulation, in contrast, contains such a low concentration of Octoxynol 40 that it does not produce micelles that solubilize the KT/BAC complex; instead, Defendants contend, the NaCl in their formulation ionically shields the KT and BAC icons, prevents them from interacting, and stabilizes the formulation.

The fundamental problem with Defendants' contention – which this Court considers fatal to Defendants' efforts to withstand summary judgment of infringement – is that Defendants do not

[1] The Court rejects Plaintiffs' contention that the reverse doctrine of equivalents defense is categorically inapplicable to disputes where chemical composition claims and/or generic copies of drugs are involved. While as a matter of logic such disputes leave very little leeway to determine that a product literally reads on the claim but is so far changed in principle from the claimed compound that it does not infringe, *see U.S. Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1253 n.9 (Fed Cir. 1989), the defense still has viability under controlling Federal Circuit precedent. The Court will therefore examine whether Defendants have met their burden of establishing a triable issue of fact regarding applicability of the defense on this record.

identify any support for their proposed "principle" of the '493 invention in the patent's claim language, specification, or prosecution history, nor in the prior art. It is these sources that determine the equitable scope of the claims. *See Scripps Clinic & Research Foundation* 927 F.2d at 1581. Yet Defendants point to nothing in the patent claims, patent specification, prosecution history, or prior art that refer, even indirectly, to the use of Octoxynol 40 to provide stability to the '493 formulations by forming micelles to prevent KT/BAC interaction. Indeed, Defendants are unable to identify any place that the term "micelle" even appears in the patent's claims, specification, or prosecution history.

Defendants' contention regarding the "principle" of the '493 invention is also inconsistent both with the claim language (as construed by the Court in *Syntex*) and the '493 specification. With respect to the claim language, this Court has already ruled that "stabilizing amount" is not a claim limitation (Plaintiff's Request For Judicial notice (hereafter "RJN"), Exh. D), a finding that, as noted above, is binding on Defendants. Defendants' efforts to import into the invention a requirement that Octoxynol 40 be present in an amount that forms micelles and stabilizes the formulation contradicts this ruling, and is tantamount to an improper attempt to "reargue claim construction issues which were already rejected by the Court." *Ciena Corp.*, 334 F. Supp. 2d at 608. Moreover, Example 3 in the specification discloses a formulation containing Octoxynol 40 in an amount of 0.004% wt/vol. (Shafroth Decl., Exh. 1 at 7:25-40), the very concentration that Defendants' expert contends cannot form micelles. (Mitra Decl., ¶¶ 34-37.) Thus, the specification itself is inconsistent with Defendants' underlying contention that the patent's central principle is for Octoxynol 40 to stabilize an interaction through micelle formation.

Defendants rely exclusively on findings made by this Court regarding the utility of the '493 patent in the Syntex matter as their basis for establishing that the principle of the '493 invention is the use of Octoxynol 40 in an amount sufficient to achieve critical micelle concentration and form micelles. Specifically, Defendants and their expert, Dr. Mitra, assert that "a person of ordinary skill in the art reading the Court's December 29, 2003 Findings/Conclusions . . . would interpret them to mean that the function and purpose of O40 is to provide 'robust' stability to the '493 patent formulations by forming micelles to prevent the KT/BAC interaction." (Opp. at 7-8, *see also* Mitra

Decl.¶¶ 25, 48.) This is plainly insufficient to meet Defendants' burden of proof regarding the equitable scope or "principle" of the '493 Patent's claims. The Court's factual findings on the issue of utility, and specifically the Court's factual findings regarding the function of Octoxynol 40 in the patented invention, were not directed towards determining the equitable scope of the '493 Patent's claims. More fundamentally, the Court's findings did not draw on the patent claims, patent specification, prosecution history, or prior art for evidentiary support. To the contrary, the Court's factual findings on the function of Octoxynol 40 were based on the evidence of expert tests, not found in the '493 file wrapper or the prior art, that were introduced by the parties into the record at the bench trial. Such evidence is simply not probative of the equitable scope of the '493 claims as issued. Defendants' reliance on this Court's prior factual findings is misplaced and cannot suffice to meet Defendants' burden of establishing the "principle" of the '493 invention.

Accordingly, Defendants' reverse doctrine of equivalents argument fails as a matter of law.[2] Summary judgment of infringement in favor of Plaintiffs is therefore appropriate.

B. Issue Preclusion Bars Defendants, At A Minimum, From Asserting Unenforceability As Well As All Invalidity Theories Other Than Obviousness.

Plaintiffs contend that issue preclusion bars Defendants from asserting in this action that the '493 Patent is unenforceable or invalid, because these issues were decided in the *Syntex* litigation.

1. The Elements Of Issue Preclusion.

Issue preclusion (sometimes called collateral estoppel) bars relitigation of issues adjudicated in an earlier proceeding if three requirements are met: (1) the issue necessarily decided at the previous proceeding is identical to the one which is sought to be relitigated; (2) the first proceeding ended with a final judgment on the merits; and (3) the party against whom collateral estoppel is asserted was a party or in privity with a party at the first proceeding. *See Reyn's Pasta Bella, LLC v.*

[2] Because Defendants' reverse doctrine of equivalents argument fails at the threshold for the reasons stated above, the Court need not resolve Plaintiffs' objections to the declaration of Dr. Mitra, Defendants' expert, nor Plaintiffs' contention that issue preclusion bars Defendants from asserting their reverse doctrine of equivalents argument. The Court is troubled by the fact that Dr. Mitra's first declaration submitted in support of Defendants' opposition nowhere acknowledges that the critical micelle concentration ("CMC") Octoxynol 40 can vary depending on the ingredients present in the formulation, and contains several potentially misleading statements as a result. (August 13, 2007 Mitra. Decl. at ¶¶ 22-26, 37.) Nonetheless, because Defendants' reverse doctrine of equivalents argument fails for other reasons, the Court does not reach the question of whether Dr. Mitra's declaration rises to the level of a "sham" declaration that must be disregarded.

Visa USA, Inc., 442 F.3d 741, 746 (9th Cir. 2006).

The second and third requirements of this test are clearly met. The Defendants here were also parties to the *Syntex* litigation. In that earlier litigation, this Court decided that the '493 patent is enforceable and not invalid, and entered judgment to that effect. (RJN, Exh. B at 60; Exh. H at 37-38, Exh. F, Exh. I.) After Defendants appealed, the Federal Circuit subsequently affirmed. (RJN, Exh. J.) Defendants' still-pending petition writ of certiorari before the United States Supreme Court does not alter the preclusive effect of this Court's earlier judgment in *Syntex*. *See Robi v. Five Platters, Inc.*, 838 F.2d 318, 327 (9th Cir. 1988).

The applicability of issue preclusion therefore turns on the first element – whether the issue necessarily decided at the previous proceeding is identical to the one which is sought to be relitigated.

With respect to enforceability of the '493 patent, Defendants do not dispute that the inequitable conduct defense/counterclaim they seek to assert in this litigation is identical to the unenforceability defense/counterclaim that they litigated and lost in Syntex. (*Compare* RJN, Ex. C at Counterclaim, ¶ ¶ 13-37 *with* Amended Answer at Counterclaim, ¶¶ 13-37 (Docket No. 23).) Accordingly, all elements of issue preclusion are met with respect to Defendants' unenforceability defense and counterclaim in this action. Issue preclusion therefore prevents Defendants from relitigating the '493 Patent's enforceability.

With respect to invalidity of the '493 patent, Defendants do not dispute that they already litigated the validity of the '493 patent in *Syntex*. However, Defendants contend that, for issue preclusion purposes, the only relevant "issues" that can qualify for issue-preclusive effect are the specific grounds for invalidity that Defendants asserted in *Syntex*. Plaintiffs counter that the relevant "issue" is the ultimate determination on patent validity itself, regardless of which sub-issues or specific grounds were asserted by Defendants in the previous litigation.

The authorities that have considered this question support Plaintiff's view and indicate that the relevant "issue" which Defendants are precluded from relitigating is the ultimate determination on patent validity itself. This Court is persuaded that the reasoning set forth in *Applied Medical Resources Corp. v. U.S. Surgical Corp.*, 352 F. Supp. 2d 1119, 1124-26 (C.D. Cal. 2005)

("*Applied*") regarding the applicability of issue preclusion in the patent invalidity context is correct. In *Applied*, applying Ninth Circuit precedent and the Second Restatement of Judgments, the district court held that the "issue" that the accused infringer was precluded from relitigating because of a prior judgment was the validity of the asserted patent claim. *Id.* at 1124-26 (citing *Kamilche Co. v. United States*, 53 F.3d 1059, 1062 (9th Cir. 1995)). The district court held that what the accused infringer argued were the "issues" – specific arguments such as anticipation by prior sale, best mode, public use, and prior publication – were "just the particular arguments raised in support of [invalidity] in the first case." *Id.* at 1125. Applying Ninth Circuit precedent, *Applied* found that issue preclusion barred the accused infringer not only from re-raising any grounds on which it had argued invalidity in the first litigation, but also the invalidity grounds newly raised in the second litigation, such as prior art anticipation and obviousness. *See id.* at 1127-28. District courts from around the country are in agreement with the result reached in *Applied*.[3] Defendants do not cite any countervailing authority, nor do they attempt to distinguish these cases.

Because it is undisputed that the validity of the '493 Patent was litigated in the *Syntex* action, the Court finds issue preclusion will prevent Defendants from relitigating the '493 Patent's validity unless an exception to the issue preclusion doctrine applies. The two arguments raised by Defendants regarding exceptions to issue preclusion are addressed below.

2. The Effect Of This Court's *In Limine* Ruling In Syntex Barring Obviousness Type Double Patenting And Best Mode Invalidity Arguments.

Defendants assert that issue preclusion should not apply, at least to two of their invalidity arguments, because "there were at least two defenses (obviousness type double patenting and best mode) that Apotex was prepared to litigate in *Syntex* but the Court dismissed those defenses during

[3] *See Crossroads Systems (Texas), Inc. v. Dot Hill Systems Corp.*, 2006 WL 1544621 at *5 (W.D. Tex. May 31, 2006) ("the overwhelming weight of authority suggests that the 'issue' that is to be given issue-preclusive effect to a judgment in the patent context is the ultimate determination on patent validity itself, not the sub-issues or the individual pieces of evidence and arguments that may have been necessary to support the validity determination"); *Advanced Display Sys. v. Kent State Univ.*, 2002 WL 14895555 at *10 (N.D. Tex. July 10, 2002) (applying issue preclusion to earlier validity determination to prevent assertion of even unasserted invalidity arguments); *Pall Corp. v. Fisher Scientific Co.*, 962 F. Supp. 210, 213 (D. Mass. 1997) (finding that for purposes of issue preclusion, a litigant cannot raise different grounds to invalidate a patent in a second suit); *Zip Dee, Inc. v. Dometic Corp.*, 905 F. Supp. 535, 537 (N.D. Ill. 1995) (applying issue preclusion to bar previously unasserted on-sale and public-use invalidity defenses). *Dana v. E.S. Originals, Inc.*, 342 F.3d 1320 (Fed. Cir. 2003), also cited by Plaintiffs, did not directly address the issue before this Court, and this Court does not rely on *Dana* in determining that issue preclusion applies here.

pre-trial due to a technical defect." (Opp. at 18:7-9). Defendants presumably are referring to this Court's May 23, 2003 *in limine* order in *Syntex*, issued approximately ten days before trial, which barred Defendants from asserting obviousness type double patenting or best mode arguments because such theories were not disclosed until the eve of trial, prejudicing Plaintiffs.

To the extent Defendants are contending that the "issues" of obviousness type double patenting and best mode were not litigated in *Syntex*, this argument is unavailing in light of the reasoning set forth in *Applied*. Defendants litigated and lost the issue of invalidity before this Court in *Syntex*, and they are now barred from relitigating that issue, regardless of whether the specific arguments concerning invalidity were raised or not raised in *Syntex*.

To the extent Defendants are contending that they did not have a "full and fair opportunity" to litigate the issue of validity during the *Syntex* litigation because of the Court's *in limine* ruling, the Court finds that Defendants have made an inadequate showing. There is no doubt that "special circumstances-such as reason to doubt the quality, extensiveness, or fairness of procedures followed in prior litigation-may warrant an exception to the normal rules of preclusion. In short, the parties must have had a full and fair opportunity to litigate." *Durkin v. Shea & Gould*, 92 F.3d 1510, 1515 (9th Cir. 1996) (citing *Montana v. United States*, 440 U.S. 147, 155, 164 n.11 (1979)). Here, however, Defendants make no showing that the procedures followed in the *Syntex* litigation that resulted in the exclusion of obviousness type double patenting and best mode arguments – namely, enforcement of the pleading and notice requirements of the Federal Rules of Civil Procedure and this district's Patent Local Rules – were unfair to Defendants. To the contrary, this Court's decision to exclude these specific invalidity arguments from the bench trial in *Syntex* was itself based on considerations of fairness. Moreover, Defendants had an opportunity to challenge these procedural rulings as part of their direct appeal to the Federal Circuit in the *Syntex* matter.

Accordingly, this Court finds that this Court's *in limine* rulings provide no basis to depart from the ordinary rules governing issue preclusion.

3. The Effect Of The Supreme Court's *KSR* Decision Regarding The Obviousness Standard.

Defendants also contend, with respect to their invalidity attack premised on obviousness, that

the Supreme Court's recent decision in *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007) constitutes a change in law necessitating an exception to issue preclusion here. Plaintiffs respond that *KSR* does not constitute a sufficient change in law to trigger this exception to the issue preclusion doctrine.

Issue preclusion will apply to prevent relitigation of previously determined issues "unless there have been major changes in the law." *Montana v. United States*, 440 U.S. 147, 161 (1979). Legal conclusions may be reexamined only if there has been "a significant change in the legal climate." *Kamilche*, 53 F.3d at 1063 n.3; *see also Steen v. John Hancock Mut. Life Ins. Co.*, 106 F.3d 904, 914 (9th Cir. 1997).

The question of whether *KSR* constitutes a major change in the law of obviousness sufficient to preclude application of issue preclusion appears to this Court to be an issue of first impression. In *KSR*, the Supreme Court identified several problems with the "teaching, suggestion, or motivation" ("TSM") test as applied by the Federal Circuit, and found that the Federal Circuit's rigid application of the test in the case before it was inconsistent with Supreme Court precedent. 127 S. Ct. at 1741-43. *KSR*'s actual holding was narrow, as it was limited to the Federal Circuit's application of the TSM test in the matter before it, and did not purport to overrule or overturn any other decisions. Nonetheless, subsequent lower court decisions have regarded *KSR* as a decision that may affect existing Federal Circuit precedent regarding application of the TSM test.[4] None of these decisions, however, expressly considered the question of whether *KSR* is a "major change in law" for purposes of issue preclusion.[5]

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[4] *See, e.g., Izzo Golf, Inc. v. King Par Golf, Inc.*, 2007 WL 1987789 at *19 (W.D.N.Y. July 5, 2007) (permitting supplemental briefing because "KSR has substantively changed the law of obviousness"); *McNeill-PPC. Inc. v. Perrigo Company*, 2007 WL 1933931 at *15 (S.D.N.Y. July 3, 2007) ("KSR casts doubt on the continuing validity of Federal Circuit precedent on the issue of obviousness"); *MercExchange, LLC v. Ebay, Inc.*, 2007 WL 2172587 at *13 (E.D.Va.. July 27, 2007) (*KSR* "plainly raised the bar as to what qualifies as non-obvious").

[5] The Court disagrees with Plaintiffs that the Federal Circuit has already found *KSR* not to constitute a significant change in law in *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. June 28, 2007). *Takeda* did not involve a question of issue preclusion, and the Federal Circuit did not address the question relevant to this Court's inquiry – whether *KSR* constituted a significant change in law from earlier Federal Circuit precedent. Rather, *Takeda* merely applied the standards articulated in *KSR* to its direct review of the district court's findings, found that certain Federal Circuit standards for prima facie obviousness attacks upon chemical compounds remained consistent with *KSR*, and ultimately concluded the district court had not erred in holding that the accused infringer failed to establish a prima facie case of obviousness. *See id.* at 1356-61.

The Court need not resolve this question of first impression today. Even assuming, without deciding, that *KSR* constitutes a change in law sufficient to prevent application of issue preclusion to this Court's prior determination that the '493 Patent is non-obvious, Defendants are nonetheless precluded from relitigating the issue of obviousness under the claim preclusion doctrine, as discussed in more detail below.

Accordingly, the Court finds that issue preclusion bars Defendants from asserting unenforceability of the '493 Patent, and bars Defendants from asserting all invalidity theories other than obviousness. Because (as discussed below) claim preclusion bars Defendants' efforts to relitigate the question of obviousness, the Court does not decide the question of whether issue preclusion also bars this particular invalidity theory.

C. Claim Preclusion Bars Defendants From Asserting Unenforceability or Invalidity In This Litigation.

Plaintiffs contend that, as a result of the *Syntex* litigation, claim preclusion bars Defendants from asserting that the '493 Patent is unenforceable or invalid.

1. The Elements Of Claim Preclusion Are Satisfied.

Under the doctrine of claim preclusion, " [a] final judgment on the merits of an action precludes the parties or their privies from relitigating issues that were or could have been raised in that action." *Federal Dep't Stores, Inc. V. Moitie*, 452 U.S. 394, 398 (1981). Claim preclusion applies when "the earlier suit (1) involved the same 'claim' or cause of action as the later suit, (2) reached a final judgment on the merits, and (3) involved identical parties or privies." *Mpoyo v. Litton Electro-Optical Systems*, 430 F.3d 985, 987 (9th Cir. 2005) (quotations omitted).

The second and third requirements of this test are met. It is not disputed that the parties here were also parties to the *Syntex* litigation. Moreover, the Syntex litigation reached a final judgment on the merits, in which this Court decided that the '493 patent is enforceable and not invalid. (RJN, Exh. B at 60; Exh. H at 37-38, Exh. F, Exh. I.) After Defendants appealed, the Federal Circuit subsequently affirmed. (RJN, Exh. J.) Defendants contend that the resolution in *Syntex* is not yet a "final judgment on the merits" because they have filed a still-pending petition for a writ of certiorari before the United States Supreme Court. This argument is contrary to law. The preclusive effect of

a federal district court judgment is unaffected by any appeals pending therefrom. *See, e.g., Robi v. Five Platters, Inc.*, 838 F.2d 318, 327 (9th Cir. 1988).

The applicability of claim preclusion therefore turns on the first element – whether the *Syntex* lawsuit involved the same 'claim' or cause of action as this lawsuit. Defendants contend that the same claim is not at issue because the 0.4% KT ANDA formulation is materially different from the formulation at issue in *Syntex*. Plaintiffs contend that there is an identity of claims because any differences between the products are unrelated to the limitations of the claims of the '493 Patent.

For purposes of claim preclusion, the same "infringement claim" is raised by a second suit if the accused products in the two suits are "essentially the same." *Foster v. Hallco v. Manufacturing Co., Inc.*, 947 F.2d 469, 479-480 (Fed. Cir. 1991) (applying Ninth Circuit law of claim preclusion). "Colorable changes in an infringing device or changes unrelated to the limitations in the claim of the patent would not present a new cause of action" for purposes of claim preclusion. *Id.* at 480. A new claim is presented, however, if the newly accused products are "materially different" from those in the prior litigation. *See id.*[6]

Here, the undisputed record indicates that the accused products in the *Syntex* litigation and in this litigation are essentially the same. The only colorable changes identified by Defendants are "unrelated to the limitations in the claim of the patent", and therefore cannot prevent the application of claim preclusion. The formulations in the *Syntex* litigation and in this litigation contain the same identical ingredients. While the concentrations of four ingredients in the ANDA 77-308 formulation differs slightly from the formulation involved in *Syntex*, all fall well within the ranges for these ingredients claimed by the '493 Patent. (*See* Shafroth Decl., Exh. 4, Admitted Request For Admission Nos. 1-5, 7, 12 (for claims 1-4); Admitted Request For Admission Nos. 1-5, 7, 12-14, 16-17, 19-20 (for claim 5); Admitted Request For Admission Nos. 2-5, 7, 22 (for claims 15-16)). This evidence satisfies Plaintiffs' burden to demonstrate that the products are "essentially the same."

In an effort to nonetheless establish a material difference between the accused products in the two lawsuits, Defendants rely solely on the declaration of their expert, Dr. Mitra. Dr. Mitra's

[6] Defendants' contentions that the '493 Patent is invalid and unenforceable are not "claims" for purposes of claim preclusion. Instead, such assertions are treated as defenses to the patent owner's infringement claim. *See Foster*, 947 F.3d at 478-79.

declaration contains analysis and descriptions of experiments indicating that Octoxynol 40 is able to form micelles in the 0.5% KT ANDA formulation but not in the 0.4% KT ANDA formulation. (Mitra Decl., ¶¶ 42, 51.) Even if accepted as admissible testimony, however, this evidence does not establish a material difference in the two formulations.[7] The claims of the '493 Patent have no limitations relating to the stability of the formulation or to the formulation of micelles. Because the ability of Octoxynol 40 to form micelles is unrelated to the limitations of the claim of the patent, it cannot differentiate the accused formulations for purposes of claim preclusion. *See Foster*, 947 F.2d at 480; *see also Hallco Mfg. Co., Inc. v. Foster*, 256 F.3d 1290, 1295-98 (Fed. Cir. 2001).

2. No "Change Of Law" Or Fairness Exception Prevents Claim Preclusion Here.

Alternatively, pointing to the Supreme Court's decision in *KSR*, Defendants contend that even if the elements of claim preclusion are satisfied, principles of fairness dictate that claim preclusion should not apply when there has been a change in the law. This contention is contrary to governing law and miscomprehends *res judicata* principles.

Under controlling precedent from the Supreme Court and the Ninth Circuit,[8] the fact that a judgment may have been wrong, or have rested on a since-repudiated legal principle, does not alter the claim preclusive effect of a final judgment. *See Federated Dept. Stores, Inc. v. Moitie*, 452 U.S. 394, 398 (1981) ("Nor are the res judicata consequences of a final, unappealed judgment on the merits altered by the fact that the judgment may have been wrong or rested on a legal principle subsequently overruled in another case."), *Chicot County Drainage Dist. v. Baxter State Bank*, 308 U.S. 371, 374-75 (1940) (claim preclusion applied even though statute upon which prior case was decided was subsequently declared unconstitutional); *Clifton v. Atty. Gen. Of State of Cal.*, 997 F.2d 660, 663 (9th Cir. 1993) ("For us to conclude, under the facts of this case, that the district court's order has become an 'instrument of wrong' merely because it rests on a since repudiated rationale would be to nullify the doctrine of res judicata."); *Government of Guam v. Cruz*, 869 F.2d 1326,

[7] Because Dr. Mitra's testimony would not suffice to establish a material difference in the formulations, the Court need not resolve Plaintiffs' objections to the declaration of Dr. Mitra.

[8] For purposes of analyzing the claim preclusive effect of judgments in patent cases, the law of the regional circuit, not of the Federal Circuit, controls. *See Hartley v. Mentor Corp.*, 869 F.2d 1469, 1471 n.1 (Fed. Cir. 1989); *Foster*, 947 F.2d at 477 n.7.

1327 (9th Cir. 1989) (claim preclusion prevents relitigation of dispute "even if the court in the first litigation was wrong in its determinations").[9]

Defendants cite to no authority supporting their position that principles of fairness create an exception to ordinary claim preclusion principles where a change in law has occurred.[10] To the contrary, the Supreme Court has counseled courts against case-by-case evaluation of the equities when applying claim preclusion principles:

> The doctrine of res judicata serves vital public interests beyond any individual judge's ad hoc determination of the equities in a particular case. There is simply no principle of law or equity which sanctions the rejection by a federal court of the salutary principle of res judicata....[T]he mischief which would follow the establishment of precedent for so disregarding this salutary doctrine against prolonging strife would be greater than the benefit which would result from relieving some case of individual hardship.

Federated Dept. Stores, 452 U.S. at 401-02.

Accordingly, the Court finds that claim preclusion applies here to bar Defendants' contentions that the '493 Patent is invalid and unenforceable, including Defendants' contention that the '493 Patent is invalid for obviousness.

D. Scope Of Order Authorized By 35 U.S.C. § 271(e)(4).

35 U.S.C. § 271(e)(4) provides, in relevant part, that for acts of infringement described in Section 271(e)(2):

> (A) the court shall order the effective date of any approval of the drug . . . involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed.

The parties dispute the appropriate scope of an order under this statutory provision. Plaintiffs cite to 21 U.S.C. § 355a(a)(2)(B), a statutory mandate directed to the FDA, in support of their contention that the Court should issue an order requiring that the effective date of any approval

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[9] *See also* 18 Moore's Federal Practice § 131.12[3] (Matthew Bender 3d ed.) ("The doctrine of claim preclusion is not concerned with whether a prior judgment was right or wrong or whether subsequent changes in the law, the discovery of additional facts, or considerations of fairness should merit a different result in the subsequent litigation").

[10] Defendants did not address, in their opposition, the Supreme Court or Ninth Circuit authority cited by Plaintiffs. Instead, Defendants attempted to distinguish, largely unsuccessfully, certain out-of-circuit decisions that recognize the same principle that a change in law will not prevent application of claim preclusion.

of ANDA 77-308 be not earlier than the date six months after the expiration of the '493 patent.[11] Defendants contend that such an order would exceed the Court's authority by continuing to enforce an expired patent and by invading the province of the FDA, and that the Court should instead issue an order that simply tracks the language of 35 U.S.C. § 271(e)(4)(A).

The Court agrees with Defendants. 21 U.S.C.§ 355a(a)(2)(B) does not provide a sufficient basis for this Court to restrict the FDA's approval of the ANDA beyond the expiration date of the patent. Accordingly, the Court will order, consistent with 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of the drug be a date which is not earlier than the date of the expiration of the patent which has been infringed.

CONCLUSION

For the foregoing reasons, the Court finds that undisputed facts establish that Defendants' filing of ANDA 77-308 infringes claims 1-5, 15-16 of U.S. Patent No. 5,110,493, and **GRANTS** summary judgment in favor of Plaintiffs on Count One of Plaintiff's complaint on that basis. The Court further finds, applying claim and issue preclusion principles as described above, that Defendants may not relitigate this Court's prior judgment the '493 Patent is enforceable and not invalid. Accordingly, the Court **GRANTS** summary judgment in favor of Plaintiffs on Defendants' counterclaim and defenses relating to invalidity and unenforceability.

Pursuant to 35 U.S.C. § 271(e)(2)(A), the Court further **ORDERS** that the effective date of any approval of ANDA 77-308 be a date which is not earlier than the date of the expiration of the '493 Patent.

IT IS SO ORDERED.

Dated: September 11, 2007

MARTIN J. JENKINS
UNITED STATES DISTRICT JUDGE

[11] 21 U.S.C. § 355a(a)(2)(B) provides that where the FDA has granted pediatric exclusivity to the listed drug, as the FDA has done for ACULAR® LS, "the period in which an [ANDA] may not be approved . . . shall be extended by a period of sixth months after the date the patent expires."